## REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 1, 2, 11, and 14-61 are requested to be cancelled, without prejudice or disclaimer.

Claims 3, 9, 12, 13, and 62 are currently being amended. Support for these amendments can be found throughout the specification as-filed, including the original claims. No new matter is being added.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 3-10, 12-13, and 62 are now pending.

### I. Claim Rejections – 35 U.S.C. § 101

Claims 3-10, 12, 13, and 62 stand rejected under 35 U.S.C. § 101 because the claimed invention is allegedly "not supported by either a specific and substantial utility or a well established utility." Similarly, the Office Action rejects claims 3-10, 12, 13, and 62-66 under 35 U.S.C. § 112, first paragraph, because in the alleged absence of utility, one of skill in the art would not know how to use the invention. Applicants respectfully traverse this ground of rejection.

As discussed in Applicants' submission accompanying the Request for Continued Examination (RCE) filed August 22, 2005, at pages 10-11, the claimed polypeptides and polynucleotides encoding them are "chemokines of the C-C family..., which are highly expressed in the pancrease. *See e.g.*, specification at 8, 2nd full paragraph. In addition to stating that the claimed polypeptides and polynucleotides encoding them are chemokines, the

specification states that the chemokines "can lead to activation of ...T lymphocytes... and/or other cells...." *Id.* This assertion is verified by Nagira *et al.*, J. BIOL. CHEM. 272:19518-24 (1997) ("Nagira"), which states that the identified chemokine "is specifically chemotactic for lymphocytes." Nagira at 19519, first full paragraph. Because the activation of lymphocytes is known to be associated with inflammation, one of skill in the art could use the disclosed chemokines for a variety of applications, such as assays to assess inflammation. Thus, the specification discloses a "specific and substantial" utility.

The Office Action states that "while applicant may have identified a C-C type chemokine, this designation does not speak specifically to the functioning of the molecule with regard to target, and further experimentation (which is unpredictable) would be required to determine such a target." However, the specification states that the recited chemokines "can lead to activation of ...T lymphocytes," a statement verified by Nagira. Thus, the specification does disclose one specific function of the recited chemokines.

The Office Action argues that the "language of the specification appears to be prophetic" and that the statements are "not a definitive assertion of functionality to utility." Office Action at 6. The specification does not need to provide a definitive statement of utility. It is sufficient to provide a statement of how the chemokines "can" be used. In addition, the passage clearly states that expression of chemokines will result in some kind of immune system cell activation, even assuming arguendo that the passage does not unequivocally provide the exact target(s). Such a statement is sufficient to establish utility of the claimed invention, because one of skill in the art would readily understand how to use compounds which activate immune cells.

Moreover, stating that the claimed protein is a pancreatic expressed chemokines is, itself, sufficient to establish utility. The Federal Circuit recently discussed the utility requirement in a case where the claimed invention was directed to expressed sequence tags (ESTs), which "do not correlate to an underlying gene of known function." *In re Fisher*, 421 F.3d, 1365, 1374 (Fed. Cir. 2005). The court determined that the ESTs lacked utility because the patentee did "not identify the function for the underlying protein-encoding genes." *Id.* at 19. In doing so, the court analogized the case to other cases where the patentee had a bare

assertion of "biological activity." Here, the specification does more than provide a bare assertion of "biological activity" and, instead, states that the recited polypeptide possesses pancreatic expressed chemokine activity. Accordingly, the application provides sufficient assertions of specific and substantial utility.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

## II. Claim Rejections – 35 U.S.C. § 112, First Paragraph

Claims 3, 6-8, 9, 12, 13, and 62 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Essentially, the claims were rejected because variants, biologically active fragments, and immunogenic fragments of SEQ ID NO. 4 are allegedly not described in the instant specification. Applicants respectfully traverse this ground of rejection.

As discussed in Applicants' submission accompanying the RCE filed August 22, 2005, at pages 12-13, a skilled artisan would understand the as-filed specification to demonstrate possession of the claimed genus. Indeed, the specification provides representative amino acid and nucleic acid sequences and methods of forming variants of the sequences. In addition, the specification states that these polypeptides are chemokines (*see* Section I above). One of skill in the art can readily determine and screen compounds for chemokine activity as evinced by Example XII, for example. Specification at 21. As discussed below, PTO guidelines and applicable law make clear that this disclosure provides a complete description of the claimed genus from the perspective of one of ordinary skill in the art.

The PTO has provided guidelines for determining whether the written description requirement is satisfied where a claim recites a "Product by Function." *See* "Revised Interim Written Description Guidelines Training Materials," [hereinafter "Guidelines"] available at http://www.uspto.gov/web/menu/written.pdf. In particular, Example 14 provides circumstances under which a claim to a protein recited by SEQ ID NO and variants thereof that are "at least 95% identical" to the SEQ ID NO are fully supported by the specification.

As indicated in Example 14, a "[specification] meets the requirement of 35 U.S.C. 112, first paragraph, as providing adequate written description for the claimed invention," where:

> The specification exemplifies a protein...that [has an activity]. The isolated protein was sequenced and determined to have the sequence as set forth [by] SEQ ID NO:[#]. The specification also contemplates but does not exemplify variants of the protein wherein the variant can have any or all of the following: substitutions, deletions, insertions and additions. The specification indicates that procedures for making proteins with substitutions, deletions, insertions and additions is routine in the art and provides an assay for detecting the [activity] of the protein.

Under these circumstances, "[o]ne of skill in the art would conclude that applicant was in possession of the necessary common attributes possessed by the members of the genus" recited by the claim. *Id.*

Further, consistent with recent Federal Circuit ruling and MPEP guidelines, Applicants need not have provided explicit disclosure for each and every nucleic acid sequence that encodes a polypeptide of SEQ ID NO: 4. Specifically, the Federal Circuit recently stated that:

> The state of the art has developed such that the complete amino acid sequence of a protein may put one in possession of the genus of DNA sequences encoding it, and that one of ordinary skill in the art at the time the [application] was filed may have therefore been in possession of the entire genus of DNA sequence that can encode the disclosed [sequence], even if individual species within that genus might not have been described or rendered obvious....Moreover, we see no reason to require a patent applicant to list every possible permutation of the nucleic acid sequences that can encode a particular protein for which the amino acid sequence is disclosed, given the fact that it is . . . a routine matter to convert back and forth between an amino acid sequence and the sequences of the nucleic acid molecules that can encode it.

*See In re Wallach*, 378 F.3d 1330, 1333-34 (Fed. Cir. 2004) (citations omitted).

In addition, the MPEP states that "[d]escription of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces." Continuing, the MPEP teaches that:

> For example, in the molecular biology arts, if an applicant disclosed an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence, but not necessarily any particular species.

*See* MPEP 2163(II)(A)(3)(a)(ii) (citations omitted).

As such, Applicants need not have provided explicit disclosure for each and every nucleic acid sequence that encodes a polypeptide of SEQ ID NO: 4. Rather, because the specification discloses a polypeptide of SEQ ID NO: 4, one skilled in the art would recognize that Applicants were in possession of the genus of DNA sequences encoding SEQ ID NO: 1. For example, it is well-known in the art that an amino acid may be encoded by more than one codon triplet. The genus of DNA sequences that may encode a full-length protein includes those sequences that are divergent by virtue of being degenerate in sequence. Further, as noted above, one skilled in the art would recognize that, just as there exists degeneracy of the DNA code, there similarly exist amino acid substitutions that can be made to a polypeptide, which are conservative in nature and which do not alter the basic properties of the residue that is replaced. *See* Application at page 6, last full paragraph.

In addition, Applicants have amended the claims, without acquiescing in the propriety of the rejection, to no longer recite (a) "a biologically active fragment" or (b) "an immunogenic fragment."

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

## III. Claim Rejections – 35 U.S.C. § 102

Claims 3, 6-9, 12 and 62 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by WO 92/19737 to Yamagishi *et al.* ("Yamagishi"). According to the Office Action, Yamagishi anticipates the claims by disclosing "a polynucleotide that encodes residues 75-79 of instant SEQ ID NO: 4." Office Action at 14. Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

The presently amended claims are not anticipated by Yamagishi, because Yamagishi does not teach or suggest an isolated polynucleotide encoding SEQ ID NO: 4 or a polypeptide variant of "SEQ ID NO: 4, wherein the variant has chemokine activity and: (i) an insertion or deletion of 1-5 amino acids as compared to SEQ ID NO: 4; (ii) one amino acid substitution as compared with SEQ ID NO: 4; or (iii) a combination of (i) and (ii)." Instead, Yamagishi discloses "a polynucleotide that encodes residues 75-79 of instant SEQ ID NO: 4." Thus, the polynucleotide of Yamagishi has far more alterations than permitted by the present claims. Accordingly, Yamagishi cannot anticipate the claims.

In addition, Applicants have amended claim 12 to recite "the amino acid sequence" rather than "an amino acid sequence." Thus, the rejection of claim 12 is rendered moot.

## CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to

Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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